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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/728,423	12/01/2000	Michael Houghton	1618.003	3252

27476 7590 03/13/2006

Chiron Corporation  
Intellectual Property - R440  
P.O. Box 8097  
Emeryville, CA 94662-8097

EXAMINER

HILL, MYRON G

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/728,423

Applicant(s)

HOUGHTON ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 3-6, and 8- 27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, and 8- 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                                               |                                                                                         |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                              | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                          | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/19/05</u> . | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

This action is in response to the paper filed 19 December 2005.

Claims 1, 3-6, and 8- 45 are under consideration.

#### ***Information Disclosure Statement***

A signed and initialed copy of the IDS paper filed 12/19/05 is enclosed.

#### ***Rejections Maintained***

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-6, 8-10, 14, 15, 17, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton *et al.* (EP0318216) and Fields.

The claims are drawn to a method of eliciting humoral immune response by administering HCV E2 or E1/E2 polynucleotide constructs.

Applicant addresses all the obvious type rejections together and addresses each reference in turn, pointing out the deficiencies in each reference.

Applicant argues that the references must teach or suggest all the limitations and that the examiner cannot use hindsight reasoning.

Applicant's arguments have been fully considered and not found persuasive.

Applicant has not argues that the sizes of HCV E1 and E2 are not those as listed in Fields (page 1037 Figure 1). It was known that E1 and E2 are not secreted and that deletion mutants are secreted (Fields page 1037 column 2, top and bottom). This is an inherent property of the proteins, not a new ground of rejection. Houghton suggest polynucleotides from envelope proteins (E1 and E2), not secreted forms.

Houghton teaches DNA delivery, Fields is used to show E1 and E2 were known in the art at the time of invention and the properties associated with them.

The other references are used to show other limitations in the claims or assays known in the art. Applicant asserts the prior art teaches away from the non secreted form (listing page 17 of the specification). Houghton as mentioned above does not teach the use of truncated forms or secreted forms.

Applicant has not pointed out any specific limitations that have not been met.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections

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are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Thus, the rejection is maintained.

Claims 3 and 18-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton et al. (EP0318216) and Fields as applied to claims 1, 3-6, 8-10, 14, 15, 17, and 26 above, and further in view of Ishii et al. (previously cited).

The rejection is maintained for reasons as addressed above.

### ***Rejections Necessitated By Amendment***

#### ***Claim Rejections - 35 USC § 103***

Claims 1, 3-6, 8-17, and 27-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Houghton et al. (EP0318216) and Fields as applied to claims 1, 3-6, 8-10, 14, 15, 17, and 26 above, and further in view of Nielson (AMPIS 1998, previously cited), or Singh et al.

Applicant added claims 28-40 which include the same limitations to those in claims 11-13, 16, and 27.

The art specific for these claims was addressed in the prior Office Action and in light of Applicant's response, they are addressed above.

Thus, the method is *prima facie* obvious as discussed in the prior action.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

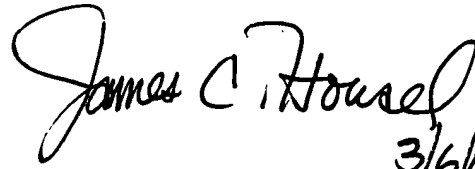
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Myron G. Hill  
Patent Examiner  
3 March 2006

  
JAMES HOUSEL  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
3/6/06